In the Office Action, page 4, lines 9, the Examiner stated "Review of the prosecution history of the instant application indicates that the office originally maintained a 112 first paragraph rejection over a non-murine pluripotential embryonic stem cell because the specification failed to provide the necessary guidance to overcome the unpredictability of creating an embryonic stem cell from any other animal besides the mouse." Thus, applicant's cancellation of claims 1-3 renders this basis of the rejection moot as early human pluripotential stem cells are claimed.

REJECTION UNDER 35 U.S.C 112

Claims 1-4 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a non-murine mammalian pluripotential cell, allegedly does not provide enablement for such a cell having a normal karyotype.

As discussed in the interview, applicant believes the examiner has misread the data. The data clearly shows that pluripotential stem cells having a normal karyotype can be obtained by applicant's methods. Specifically, as shown on page 19, lines 17-20, most of applicant's cells had a normal or near normal karyotype. It is not relevant that two of the lines had a significant proportion of trisomic cells since most of the cells were normal. Importantly, EC cells are derived from abnormal cells. Unlike EC cells, applicants are starting with normal cells. Thus it would be predictable that if one started with normal cells and obtained cells with a normal karyotype for one species, one would expect to obtain cells having a normal karyotype from other species. The examiner has provide no scientific reasons why one would not expect to

obtain cells having a normal karyotype for the claimed human cells given applicants are starting with normal human cells and the data showing pluripotential stem cells having a normal karyotype for mice. Thus, applicants have enabled human pluripotential stem cells having a normal karyotype.

Clearly, the case law does not require operability of every cell made that could potentially fall under applicants claimed invention, only that one of skill in the art can practice the invention without undue experimentation. (See *In re Wands*, 858 F.2d 734, 740 (Fed. Cir. 1988), where numerous attempts to obtain the claimed antibodies failed, but because the antibodies could be obtained by testing, the claims were found enabled.). In addition, it is well recognized that cells of the type claimed by applicant have a normal karyotype. See Dovonvan et al., Nature, Vol. 414, Nov. 2001, p. 92-97, especially table 1, which shows EC cells have an heteroploid karyotype while ES and EG cells have a euploid karyotype.

Therefore, applicants have clearly enabled human pluripotential stem cells having a normal karyotype and removal of the rejection on this basis is respectfully requested.

Claims 1-4 also stand rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As discussed above and in the interview, while applicants assert the claim language was clear and unambiguous as written, they have canceled claims 1-3 and amended claim 4 to remove the objected language. Thus, the rejection is rendered moot.

REJECTIONS UNDER 35 U.S.C. 102

Claims 1-3 stand rejected as allegedly anticipated in view of Wheeler and Norarianni et al. As noted above, claims 1-3 have been canceled without prejudice. Thus, this rejection is rendered moot.

Applicants respectfully acknowledge withdrawal of the rejection under U.S.C. § 112, first paragraph, and the double patenting rejection.

Pursuant to the above remarks, allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Payment in the amount of $640.00 ($460.00 3-month Request for Extension of Time and $180.00 Submission of Information Disclosure Statement) is to be charged to a credit card and such payment is authorized by the signed, enclosed document entitled: Credit Card Payment Form PTO-2038. This amount is believed to be correct; however, the Commissioner is hereby

authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

David G. Perryman
Registration No. 33,438

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811
Phone: (404) 688-0770

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence and anything indicated as included with this correspondence is being transmitted via Facsimile No. 703-305-3014 to: Examiner Joseph Woitach, Group Art Unit 1632, U.S. Patent and Trademark Office, on the date shown below.

David G. Perryman

12-20-01
Date